| ARL Analytical Research Laboratories | Form |
|---|---|
| Document Number: QUF-113-V4 | Implementation / Revision Date: 06/08/12 |
| Document Title: Microbiology Out-of-Specification Investigation | |

## 1. Description of OOS Results:

| | |
|---|---|
| ARL No: 182466 | Date: 08/09/12 |
| Client: New England Compounding Center | Sample Description Bacitracin 50,000 units in 20ml 0.9% NaCl |
| Lot # 07232012@125 | Analyst: Ben Wronowski |
| Test performed: Sterility (Open Membrane Filtration) | Date Tested: 07/25/12 |
| Limit: Sterile / Not Sterile | OOS Result: Not Sterile |

## 2. OOS Review:

| | Acceptable: |
|---|---|
| Negative Control | Yes ☑ No ☐ |
| Environmental Monitoring | Yes ☐ No ☑ |
| Media Validated | Yes ☑ No ☐ |
| Method Validated (B/F) | Yes ☐ No ☑ |
| Personnel training current | Yes ☑ No ☐ |
| Filter Membrane | Yes ☑ No ☐ N/A ☐ |
| Direction Inoculation | Yes ☐ No ☑ N/A ☐ |

## 3. Additional analysis

| | |
|---|---|
| Gram-stain of sample contamination | Positive ☑ Negative ☐ N/A ☐ |
| Gram stain of Env. Mon. | Positive ☑ Negative ☐ N/A ☐ |
| Media contaminated - liquid | aerobic ☑ anaerobic ☐ N/A ☐ |
| solid | aerobic ☐ anaerobic ☐ PDA ☐ N/A ☑ |
| Type of contaminant | bacterial ☑ fungal ☐ |



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Day Growth Observed: 14

Descriptions of colony morphology of contaminant and EM.
Sample Contaminant - Circular, Entire, punctiform, Dull
EM - Irregular, curled, Raised, Large, Dull
Gram Stain
Sample Contaminant - Gram Positive cocci
EM - Gram Positive Rod

Notify Client: Yes/No

Person Contacted – Name, number and Time
Annette Robinson 508-656-2635 08/08/12 11:00 Voicemail
Annette Robinson Barry Cadolin 08/09/12 E-mail
Invalidate initial result: Yes/No & Why
Sample Contaminant and Environmental Monitoring contaminant were not similar in colony morphology or Gram Stain.

Retest: Yes/No Retest Result: Sterile/ Not Sterile

Supplemental Report Issued: Yes/No

Bacterial/Fungal Identification Requested: Yes/No

If yes, what was identified? _____



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Comments: Spoke with Annette and they did not want a bacterial ID and they have decided to discard the lot.

Investigator: [illegible] Date: 08/10/12

PHONE ( 271-1144 FAX ( -1174

7/25/12 Microl TDH AA 8/14/12 BW

| | | * | ** | | *** | | Colony Morphology/Gram-Stain/Genus Species |
|---|---|---|---|---|---|---|---|
| TSA | 400 | 2 | EG1 L | D | 0 | 0 | |
| TSA | 400 | 2 | EG2 L | D | 0 | 0 | |
| TSA | 400 | 2 | EG2 R | D | 0 | 0 | |
| TSA | 400 | 2 | EG1 R | D | 0 | 0 | NA TDH 10/9/12 |
| TSA | 400 | 3 | EG2 G | A | 0 | 0 | |
| TSL ~~TSA~~ | 1001405150 ~~400~~ | 1 ~~3~~ | EG1 G | EE TDH 10/9/12 ~~B~~ A | 0 | 0 | |
| TSL | 1001405150 | 3 | EG1 C | B | 0 | 0 | |
| TSL | 1001405150 | 3 | EG1 W | B | 0 | 0 | |
| TSL | 1001405150 | 1 | EG2 A | B | 0 | 0 | |
| TSL | 1001405150 | 3 | EG2 B | B | 0 | 0 | |
| TSL | 1001405150 | 3 | EG2 LW | B | 0 | 0 | |

*1 = active air; 2 = passive air; 3 = surface sample
** reference sample location descriptions in MBI-106
*** reference acceptance criteria in MBI-106

Microbiologist — 8/14/12 Date — THyde Review — 10/19/12 Date



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